

## REMARKS

Claims 1-23 are pending in the Office Action. Though the Examiner mistakenly asserts that claims 3-10 and 13-16 are withdrawn, Applicant respectfully points out that claims 10 and 13-16 are the claims that have been previously withdrawn. The Examiner's rejections will now be respectfully addressed, beginning with the 112 rejection.

### Rejections under 35 U.S.C. §112, second paragraph

Claims 1-12 and 17-23 have been rejected under 35 U.S.C. §112, second paragraph for allegedly failing to point out and distinctly claim the subject matter that Applicant regards as the invention. The Examiner specifically takes issue with the meaning of the term glycomacroprotein. Applicant respectfully traverses the rejection.

Referring to Applicant's specification, particularly pages 10-13, Applicant respectfully asserts that the term *glycomacropeptide* (GMP) is sufficiently defined. As stated in the Specification, it is a casein derived whey peptide that includes a peptide backbone with saccharide groups attached thereto. In an exemplary embodiment, GMP is derived from k-casein when milk is treated with chymosin during cheesemaking. In this exemplary process, hydrolyzing the milk glycoprotein k-casein creates two peptides; para-k-casein and GMP.

Applicant respectfully submits that the description of GMP found in the Specification sufficiently defines GMP, and does so with reference to glycoproteins, such as k-casein. Applicant further respectfully submits that the differences between glycoproteins and GMP are generally known to one of ordinary skill in the art. That is, generally speaking, glycoproteins (such as those found in mucin) are high molecular weight proteins that may have many different structures, while GMP (as "peptide" would indicate) is a low molecular protein *fragment* of very specific structure.

Applicant is uncertain as to the Examiner's comments regarding "substantially free," as this phrase is not found in the claims of this Application, but instead is found in the claims of 10/814,001.

Applicant respectfully asserts that 112 rejection is overcome in light of Applicant's description of GMP and the remarks submitted hereinabove.

Rejections under 35 U.S.C. §103(a)

Claims 1-12 and 17-23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over any of United States Patent Number 4,923,699 to Kaufman ("Kaufman" hereinafter), United States Patent Number 6,281,192 to Leahy ("Leahy I" hereinafter), and United States Patent Number 6,429,194 to Leahy ("Leahy II" hereinafter) in view of United States Patent Number 5,830,913 to Ogawa ("Ogawa" hereinafter). Applicant respectfully traverses.

Applicant's independent claims 1 and 17 recite a "glycomacropeptide" (GMP). None of Kaufman, Leahy I, or Leahy II teaches use of (GMP). Instead each of Kaufman, Leahy I, or Leahy II teaches use of glycoprotein mucin. As discussed in the 112 remarks, (GMP) and glycoproteins include differences that are generally known in the art. Generally speaking, glycoproteins (such as those found in the mucin of Kaufman, Leahy I, and Leahy II) are high molecular weight proteins that may have many different structures, while GMP is a low molecular weight *fragment* of very specific structure (a peptide backbone with oligosaccharides attached thereto). As GMP is a fragment of a protein, it must be isolated from a protein for use in an ophthalmic solution or as a dry eye treatment. None of Kaufman, Leahy I, and Leahy II teaches use of isolated protein fragments. These references instead teach use of entire glycoproteins found in mucin. As such, none of Kaufman, Leahy I, and Leahy II teaches every element of Applicant's claims.

Since Ogawa is merely used to teach an ophthalmic preparation comprising a container and labeling, Ogawa does not overcome the deficiencies of Kaufman, Leahy I,

and Leahy II. Furthermore, Applicant's new claim 24 recites GMP including oligosaccharides and a peptide chain of 50 amino acids or less (50 amino acids or less being inherent to peptides). As Kaufman, Leahy I, and Leahy II simply teach glycoprotein mucin, they certainly do not teach GMP including oligosaccharides and a peptide chain of 50 amino acids or less.

Accordingly, for at least the reasons set forth hereinabove, Applicant's claims 1, 17, and new claim 24, and claims 2-12 and 18-23 that depend respectively therefrom, are not obvious over any of Kaufman, Leahy I, or Leahy II in view of Ogawa.

Claims 1, 4-10, and 17-23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over any of United States Patent Number 5,145,680 to Hayashi ("Hayashi" hereinafter) in view of Ogawa. Applicant respectfully traverses.

Referring to column 1, line 42, Vitronectin is a glycoprotein taught for use in Hayashi. Since Applicant's claims recite GMP, for at least the reasons set forth with regards to the rejection over any of Kaufman, Leahy I, or Leahy II in view of Ogawa, Applicant's claims 1, 4-10, and 17-23 are also not obvious over Hayashi in view of Ogawa.

#### Double patenting rejections

Claims 1-12 have been rejected on the grounds of nonstatutory type double patenting as being unpatentable over claims 1-25 of Leahy I and claims 1-21 of Leahy II. In light of the 103 arguments distinguishing Applicant's claims over Leahy I and II.

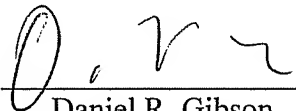
Claims 1-12 and 17-23 have also been provisionally rejected on the grounds of nonstatutory type double patenting over claims 1-2, 11-12, and 19-26 of co-pending Application Number 10/814,001. As Applicant has, at this time, decided not to pursue prosecution of the claims in 10/814,001.

Applicant believes that all of the outstanding objections and rejections have been addressed herein and are now overcome. Entry and consideration hereof and issuance of a Notice of Allowance are respectfully requested.

If there are any charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicants' attorneys.

The Office is invited to contact applicant's attorneys at the below-listed telephone number concerning this Amendment or otherwise regarding the present application.

Respectfully submitted,

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Date: March 6, 2007